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Section 6: 510(k) Summary

Trade Name:	ChitoGauze™
Common Name:	Wound Dressing
Classification Name:	Dressing
Product Code:	FRO
Predicate Device(s):	Modification to ChitoGauze™ (K090026)
Company Name:	HemCon Medical Technologies, Inc.
Company Address:	10575 SW Cascade Avenue, Suite 130 Portland, OR 97223
Contact Person:	Kevin Hawkins Director – Quality & Regulatory
Contact Phone:	(503)245.0459 x114
Contact Fax:	(503)245.1326
Date of Preparation:	29 July 2009

Description of the Device:

The ChitoGauze dressing is composed of standard polyester/rayon blend non-woven medical gauze that is coated with chitosan. This submission adds models of various dimensions to the legally marketed four inch by four yard (4" x 4 yds) dressing. ChitoGauze dressings are z-folded and packaged in a peelable foil pouch. The pouched dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6}. The hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding.

Intended Use:

ChitoGauze™ is intended to be a hemostatic wound dressing.

Indications for Use (Rx):
ChitoGauze is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Indications for Use (OTC):
ChitoGauze is intended for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.

Technological Characteristics:

Changing the dimensional size of the dressing has no effect upon the technological characteristics.

Non-Clinical Performance Data:

Biocompatibility
Biocompatibility has been demonstrated per ISO 10993. Changing the dimensional size of the dressing has no effect upon the biocompatibility.

Reduction of Microorganisms:
An eight-ply version of ChitoGauze™ that represents the smallest product size, was tested for reduction of microorganisms against the following species. The log reduction data demonstrates the level of antibacterial effectiveness. The clinical utility of these results is unknown.

Microorganism	Gram Stain	Log Reduction
Staphylococcus aureus (MRSA) ATCC 33591	+	>5.0
Staphylococcus aureus (MRSA) ATCC BAA-1556	+	>5.1
Staphylococcus epidermidis ATCC 12228	+	>4.4
Pseudomonas aeruginosa ATCC 9027	-	>5.1
Enterococcus faecalis (VRE) ATCC 51299	+	>5.4
Acinetobacter baumanii ATCC 15308	-	>5.2
Citrobacter freundii ATCC 8090	-	>5.2
Enterobacter cloacae ATCC 13047	-	>4.9
Streptococcus mutans ATCC 25175	+	>4.7
Streptococcus pneumoniae ATCC 10015	+	>5.4
Escherichia coli ATCC 8739	-	>4.9
Klebsiella pneumoniae ATCC 4352	-	>5.2
Streptococcus pyogenes ATCC 19615	+	5.0
Salmonella choleraesius ATCC 10708	-	>4.6
Stenotrophomonas maltophilia ATCC 12714	-	>5.1
Citrobacter koseri ATCC 25408	-	>4.7
Proteus mirabilis ATCC 4630	-	>5.0
Proteus vulgaris ATCC 12454	-	>4.6
Moraxella catarrhalis ATCC 8193	-	>4.9
Clostridium difficile ATCC 9689	+	>5.0
Shigella species ATCC 11126	-	>4.3
Micrococcus luteus ATCC 49732	+	>5.0
Vibrio cholerae ATCC 11558	-	>4.0
Enterobacter aerogenes ATCC 13048	-	>5.0
Enterococcus faecalis (VRE) ATCC 700802	+	>5.3
Serratia marcescens ATCC 13880	-	>4.5

Sterility
A sterility validation for ChitoGauze™ was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method. Changing the dimensional size of the dressing has no effect upon the sterility validation.

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Clinical Performance Data:

No clinical data was required for evaluation of this device.

Conclusion:

The modification to ChitoGauze to provide various dimensional sizes is neither a change to the intended use, nor an alteration of the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

HemCon Medical Technologies, Inc.
% Mr. Kevin Hawkins
Director – Quality & Regulatory
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223

AUG 2 5 2009

Re: K092357
Trade/Device Name: ChitoGauze™
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 29, 2009
Received: August 5, 2009

Dear Mr. Hawkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092357

Device Name: **ChitoGauze™**

Indications for Use (Rx):

ChitoGauze™ is a hemostatic dressing for the external, temporary control of severely bleeding wounds.

Indications for Use (OTC):

ChitoGauze™ is intended for temporary external use to stop bleeding of minor wounds, minor cuts and minor abrasions.

Prescription Use __X__ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092357